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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,736	08/02/1999	ELISABETH WOLPERT	000500-182	3510

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EXAMINER
LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
1635	18

DATE MAILED: 03/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/319,736	Applicant(s) WOLPERT ET AL.	
	Examiner Karen Lacourciere	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *13-53,55-63 and 65-142* is/are pending in the application.

4a) Of the above claim(s) *13-53,55-63,65-82 and 105-142* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 August 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group XV in Paper No. 17 is acknowledged. The traversal is on the ground(s) that the inventions are linked by a special technical feature because the reference Sanda et al. does not disclose isolated epitopes or antigens as claimed because the claimed antigens or epitopes have been isolated from cells on which they are normally expressed. This is not found persuasive because the technical feature of claim 13 has been disclosed by Sanda et al., as the claim recites that the epitopes and antigens claimed are expressed on cells.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-53, 55-63, 65-82 and 105-142 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 83-104 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Support for newly submitted claims 83-104 could not be found in the specification as filed or in the originally presented claims. Applicant points to claim 12 (b) and (c) for support for these claims and also points to various points in the specification as support for particular claims. Claim 12, however, recites a process for treatment, prevention and diagnosis of cancer and virus infections by administering cells to a body, wherein the cells are (b) especially MHC class I dependent and (c) autologous T-cells, especially MHC class I dependent and does not provide support for the general method claimed, *in vivo* and *in vitro* eliciting and stimulating immunological effector cells, and does not provide support for newly added claim limitations. The particular passages Applicant points to for support for newly added claim limitations may provide support for certain words used in these newly added claims, however, the specification does not use these words within the context of the newly claimed methods and, therefore, does not provide support for the new claims.

Applicant points to page 6, lines 21-29 and claim 12, steps b and c to support newly submitted claims 83 and 85, however, there does not seems to be any support for the methods claimed in these lines, or elsewhere in the specification. For example, page 6, lines 21-29 recite preparation of a pharmaceutical or vaccine. There is no support for the limitations antigen recognition by T-lymphocytes or T-cell receptors, lymphoid cells expressing beta-2-microglobulin, syngenic T-cells, target cells which

have not been contacted with external MHC binding peptides except for external MHC binding peptides, or even the method step of contacting target cells with immunological effector cells, for example.

Applicant points to page 7, lines 14-18 and claim 12, steps b and c to support newly submitted claim 84, however, there does not seems to be any support for the method claimed in these lines, or elsewhere in the specification. For example, page 7, lines 14-18 recites measuring downregulation of TAP-function by peptide transporter assays and expression of TAP protein can be measured by antibody assays. This does not appear to have any connection to the method of claim 84.

Applicant points to page 7, lines 4-18 to support claim 86, but these lines are concerned with antibody assays to measure MHC class I down regulation and do not appear to be related to the methods claimed.

Applicant points to page 10, lines 5-7 to support claim 87, however, there is no support for the method claimed, in particular, there is no support or the limitations (provided by dependence on claim 83) for example, antigen recognition by T-lymphocytes or T-cell receptors, lymphoid cells expressing beta-2-microglobulin, syngenic T-cells, target cells which have not been contacted with external MHC binding peptides except for external MHC binding peptides, or even the method step of contacting target cells with immunological effector cells.

Applicant points to page 10, line 9 to support claims 88 and 89, however, there is no support for the method claimed, in particular, there is no support or the limitations (provided by dependence on claim 83) for example, antigen recognition by T-

lymphocytes or T-cell receptors, lymphoid cells expressing beta-2-microglobulin, syngenic T-cells, target cells which have not been contacted with external MHC binding peptides except for external MHC binding peptides, or even the method step of contacting target cells with immunological effector cells.

Applicant points to page 10, line 9-10 to support claim 90, however, there is no support for the method claimed, in particular, there is no support or the limitations (provided by dependence on claim 83) for example, antigen recognition by T-lymphocytes or T-cell receptors, lymphoid cells expressing beta-2-microglobulin, syngenic T-cells, target cells which have not been contacted with external MHC binding peptides except for external MHC binding peptides, or even the method step of contacting target cells with immunological effector cells.

Applicant points to page 7, lines 4-18 to support claim 91 but these lines are concerned with antibody assays to measure MHC class I down regulation and do not appear to be related to the methods claimed.

Applicant points to page 10, lines 1-3 to support claims 92 and 93, however, there is no support for the method claimed, in particular, there is no support or the limitations (provided by dependence on claim 83) for example, antigen recognition by T-lymphocytes or T-cell receptors, lymphoid cells expressing beta-2-microglobulin, syngenic T-cells, target cells which have not been contacted with external MHC binding peptides except for external MHC binding peptides, or even the method step of contacting target cells with immunological effector cells.

Applicant points to 20, lines 2-3 and 28-29, page 24, lines 28-31 and page 29, lines 12-14 and Table 1 to support claim 94. These lines are directed to mouse experiments. There does not seem to be any support for the general method claimed, nor for the limitations, for example, of generally insect cells, or for genes encoding human molecules comprising beta-2 microglobulin.

Applicant points to page 6, line 26, page 20, line 3 and page 25, lines 1-4 to support claim 95. There is no apparent support for the limitation, for example, human molecules comprising beta-2 microglobulin in these lines.

Applicant points to page 9, lines 10-16 for support for claims 96, 97 and 99-104. Page 9, lines 10-16 are directed to a method wherein a patient is administered compositions which impair cellular peptide processing, this disclosed method does not include a step of contacting immunological effector cells with a cell expressing epitopes, as claimed and does not appear related to the instantly claimed methods.

Applicant points to page 8, lines 4-6 to support claim 98. These lines are directed to TAP inhibitors, but do not provide support for the method claimed, in particular, there is no support or the limitations (provided by dependence on claim 83) for example, antigen recognition by T-lymphocytes or T-cell receptors, lymphoid cells expressing beta-2-microglobulin, syngenic T-cells, target cells which have not been contacted with external MHC binding peptides except for external MHC binding peptides, or even the method step of contacting target cells with immunological effector cells.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 83-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 83 is indefinite due to the recitation "and further fulfilling at least one of the following criteria a or b:" because it is unclear what fulfills the criteria a or b. It is unclear what this phrase is modifying. Claims 84-104 are indefinite for the same reasons because of their dependence on claim 83.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 83-85, 87, 88, 90 and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Wölfel et al. (reference cited on PTO form 1449, filed June 6, 2001).

Wölfel et al. disclose a method of stimulating T-lymphocytes by contacting said T-lymphocytes with TAP deficient cell lines expressing HLA-A2 molecules which are expressed on blood cells from melanoma patients.

Therefore, Wölfel et al. anticipates claims 83-85, 87, 88, 90 and 91.

Claims 83-86, 90 96, 97 and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al. (Scand. Journal of Immunology Vol. 42, 1995, p 66-75).

Zhou et al. disclose a method of stimulating T-lymphocytes by contacting T-lymphocytes with TAP deficient T2K Sendai virus cells. Zhou et al. further disclose their methods wherein the cells are treated with agents that inhibit cellular peptide processing, for example, BFA.

Therefore, Zhou et al. anticipates claims 83-86, 90, 96, 97 and 99.

Claims 83-86, 90, 96, 97 and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (Journal of Immunology Vol 154, No. 7, 1995, p 3147-3155).

Liu et al. Disclose a method of stimulating T-lymphocytes by contacting T-lymphocytes with TAP deficient T2K Sendai virus cells. Liu et al. further disclose their methods wherein the cells are treated with agents that inhibit cellular peptide processing, for example, BFA.

Therefore, Liu et al. anticipates claims 83-86, 90, 96, 97 and 99.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action and Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 06-06-01 prompted

the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i) and § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 13-53, 55-63, 65-82 and 105-142 drawn to an invention nonelected with traverse in Paper No. 17. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

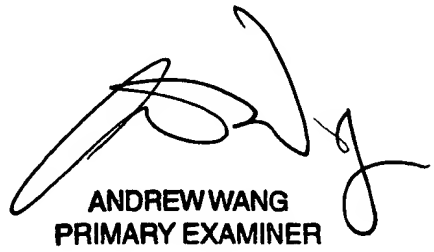
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
March 21, 2002



ANDREW WANG
PRIMARY EXAMINER